## REMARKS/ARGUMENTS

Claims 1-24 are pending in this Application.

Claims 6-8, 16-17, and 20-24 are currently amended. Applicants submit that support for the claim amendments can be found throughout the specification and the drawings.

Claims 1-24 remain pending in the Application after entry of this Amendment. No new matter has been entered.

In the Office Action, claims 1-24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by non-patent literature entitled "SmarTeam™ FDA Compliance Technical Paper Functional Compliance With FDA Rule 21 CFR Part 11" (hereinafter "SmartTeam").

**Objections to the Specification**

The Office Action objected to the Specification indicating that the reference to application numbers needs to be updated. Applicants have amended the Specification to include the reference to application numbers as requested in the Office Action, thus, Applicants respectfully request reconsideration and withdrawal of the objections to the Specification.

**Objections to the Claims**

The Office Action to claims 6-8, 16-17, and 23-24 due to informalities. Applicants have amended claims 6-8, 16-17, and 23-24 to correct the informalities as requested in the Office Action, thus, Applicants respectfully request reconsideration and withdrawal of the objections to claims 6-8, 16-17, and 23-24.

**Double Patenting**

The Office Action provisionally rejected claims 1-24 of the present Application over claims 1-25 of co-pending Application No. 10/731,299 (hereinafter the '299 Application) using obviousness-type double patenting. The Office Actions alleges that claims 1-24 of the present Application are not patentably distinct from claims 1-25 of the '299 Application because claims 1-25 of the '299 Application anticipate the claims of the present Application. Applicants respectfully disagree.

Applicants respectfully submit that claims 1-24 of the present Application are patentably distinct from claim 1-25 of the '299 Application. Applicants respectfully submit that a person of ordinary skill in the art would not conclude that the invention recited in claim 1-24 of the present Application are anticipated by, or are obvious an variation of, the invention defined in claims 1-25 of the '299 Application. For example, claim 1 of the '299 Application recites a method of collecting an electronic signature for an electronic record stored in a database. As recited in claim 1 of the '299 Application, an electronic record is automatically created from data stored in a plurality of different database tables in response to the occurrence of a predetermined event. An instance of the electronic record is then stored in a common repository of electronic records that provides an audit trail that cannot be altered or disabled by users of the system. A rule associated with the electronic record is executed to determine whether an electronic signature is required to connote review and/or approval of the electronic record. If execution of the rule results in a determination that an electronic signature is required, the instance of the electronic record is marked as unsigned, and a request to collect the required electronic signature is initiated. Thus, claim 1 of the '299 Application recites a method of collecting an electronic signature to approve an electronic record. (Emphasis added).

Applicants respectfully submit that this is substantially different from claims 1-24 pending in the present Application. In contrast to claim 1 in the '299 Application, claim 1 of the present Application recites a method of intercepting a transaction instantiated by a database application to determine if an electronic signature is necessary to commit the transaction to the database. As recited in claim 1 of the present Application, the method comprises:

in response to a triggering action generated by the database application, calling an application program interface to raise an event;

initiating a workflow process that executes a rule to determine if an electronic signature is required to approve the transaction; and

if execution of the rule results in a determination that an electronic signature is required for the transaction, instantiating a signature collection process.

Thus, claim 1 of the present Application recites a method for intercepting a transaction instantiated by a database application to determine if an electronic signature is necessary to commit the transaction to the database. (Emphasis added).

For example, claim 1 of the '299 Application recites that a rule associated with the electronic record is executed to determine whether an electronic signature is required to connote review and/or approval of the electronic record. (Emphasis added). In contrast, claim 1 of the present Application recites initiating a workflow process that executes a rule to determine if an electronic signature is required to approve the transaction. (Emphasis added). Thus, the electronic signatures are request for different types of objects: for an automatically created electronic record stored in a common repository in claim 1 of the '299 Application and for a transaction to be committed to a database in claim 1 of the present Application.

Furthermore, claim 1 of the present Application recites calling an application program interface to raise an event in response to a triggering action generated by the database application. The above feature is missing from the claims of the '299 Application. Moreover, calling an application program interface to raise an event in response to a triggering action generated by the database application is quite different from claim 1 of the '299 Application that recites a method that creates an electronic record is automatically from data stored in a plurality of different database tables in response to the occurrence of a predetermined event. (Emphasis added).

Applicants thus submit that claims 1-24 of the present Application are patentably distinct from claims 1-25 of the '299 Application. Applicants respectfully submit that a person of ordinary skill in the art would not conclude that the invention defined in claims 1-24 of the present Application is anticipated by, or would have been an obvious variation of, the invention defined in claims 1-25 of the '299 Application. Applicants thus submit that the double patenting rejection using co-pending Application No. 10/731,299 should be withdrawn.

The Office Action further provisionally rejected claims 1-24 of the present Application over claims 1-26 of co-pending Application No. 10/731,655 (hereinafter the '655 Application) using obviousness-type double patenting. The Office Actions alleges that claims 1-24 of the present Application are not patentably distinct from claims 1-26 of the '299

Application because claims 1-26 of the '655 Application anticipate the claims of the present Application. Applicants respectfully disagree.

Applicants respectfully submit that claims 1-24 of the present Application are patentably distinct from claim 1-26 of the '655 Application. Applicants respectfully submit that a person of ordinary skill in the art would not conclude that the invention recited in claim 1-24 of the present Application are anticipated by, or are obvious an variation of, the invention defined in claims 1-26 of the '655 Application. For example, claim 1 of the '655 Application recites a committing a transaction to a database. As recited in claim 1 of the '655 Application, a database transaction is initiated. An electronic record is then created that includes transaction data from the database transaction. A rule associated with the electronic record is executed to determine whether an electronic signature is required to connote review of the electronic record. The electronic signature is then requested prior to committing the database transaction to the database based on a determination that an electronic signature is required.

Applicants respectfully submit that this is substantially different from claims 1-24 pending in the present Application. In contrast to claim 1 in the '655 Application, claim 1 of the present Application recites a method of intercepting a transaction instantiated by a database application to determine if an electronic signature is necessary to commit the transaction to the database. As recited in claim 1 of the present Application, the method comprises:

in response to a triggering action generated by the database application, calling an application program interface to raise an event;

initiating a workflow process that executes a rule to determine if an electronic signature is required to approve the transaction; and

if execution of the rule results in a determination that an electronic signature is required for the transaction, instantiating a signature collection process.

For example, claim 1 of the '655 Application recites that a rule associated with the electronic record is executed to determine whether an electronic signature is required to connote review of the electronic record. (Emphasis added). In contrast, as discussed above, claim 1 of the present Application recites initiating a workflow process that executes a rule to determine if an electronic signature is required to approve the transaction. (Emphasis added).

Thus, the electronic signatures are request for different types of objects: for an electronic record in claim 1 of the '655 Application and for a transaction to be committed to a database in claim 1 of the present Application.

Furthermore, claim 1 of the present Application recites calling an application program interface to raise an event in response to a triggering action generated by the database application. The above feature is missing from the claims of the '655 Application.

Applicants thus submit that claims 1-24 of the present Application are patentably distinct from claims 1-26 of the '655 Application. Applicants respectfully submit that a person of ordinary skill in the art would not conclude that the invention defined in claims 1-24 of the present Application is anticipated by, or would have been an obvious variation of, the invention defined in claims 1-26 of the '655 Application. Applicants thus submit that the double patenting rejection using co-pending Application No. 10/731,655 should be withdrawn.

**Claim Rejections Under 35 U.S.C. § 101**

Applicants respectfully traverse the rejections to amended claims 20-24 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 101.

**Claim Rejections Under 35 U.S. C. § 102(b)**

Applicants respectfully traverse the rejections to claims 1-24 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) based on SmartTeam.

Applicants respectfully note that to anticipate a pending claim, a prior art reference must provide, either expressly or inherently, each and every limitation of the pending claim. (M.P.E.P. § 2131).

The Office Action alleges that SmartTeam teaches or suggests all of the claim limitations of claims 1-24. However, based on the arguments presented below, Applicants respectfully submit that SmartTeam fails to teach or suggest at least one of the claim limitation recited in each of claims 1-24.

**Claim 1**

Claim 1 recites a method of intercepting a transaction instantiated by a data base application to determine if an electronic signature is necessary to commit the transaction to the database, the method comprising:

in response to a triggering action generated by the database application, calling an application program interface to raise an event;

initiating a workflow process that executes a rule to determine if an electronic signature is required to approve the transaction; and

if execution of the rule results in a determination that an electronic signature is required for the transaction, instantiating a signature collection process.

Applicants respectfully submit that SmartTeam fails to teach or suggest each and every claim limitation recited in claim 1.

The Office Action alleged that SmartTeam discloses the feature of "in response to a triggering action generated by the database application, calling an application program interface to raise an event" in section 2.2 of SmartTeam. Applicants respectfully disagree.

SmartTeam merely presents a side-by-side comparison of FDA regulations to features of the SmartTeam software. In section 2.2, entitled "11.50, 11.70 Signature Manifestation and record linking," SmartTeam discloses that the SmartTeam software "tracks modification and life cycle operations," includes an approval function that "allows approving users through a workflow process…to electronically sign records," includes a server side mechanism to "silently integrate the signature into managed file," and allows an administrator to view the audit trail. SmartTeam further disclose that the user information on the records is saved "to document when a user created/uploaded or signed the records."

However, SmartTeam fails to teach or suggest the feature recited in claim 1 of "in response to a triggering action generated by the database application, calling an application program interface to raise an event." The fact the SmartTeam software tracks modification and life cycle operations, allows users to electronically sign records, or includes a server side mechanism to integrate signatures into managed files does not disclose that an application

program interface is called as recited in claim 1 to raise an event in response to a triggering action generated by a database application.

Further, claim 1 recites the feature of "initiating a workflow process that executes a rule to determine if an electronic signature is required to approve the transaction." SmartTeam merely indicates in section 2.2 that approving users can electronically sign records through a workflow process. However, simply electronically signing a record as in SmartTeam though a workflow process does not necessarily teach or suggest that a workflow process is initiated that executes a rule to determine if an electronic signature is required to approve a transaction as recited in claim 1. SmartTeam fails to teach or suggest that a rules is executed to determine is an electronic signature is required to approve a transaction as recited in claim 1.

Additionally, claim 1 recites the feature of "if execution of the rule results in a determination that an electronic signature is required for the transaction, instantiating a signature collection process." Again, SmartTeam fails to teach or suggest that if execution of a rule results in a determination that an electronic signature is required for a transaction, a signature collection process is then instantiated. SmartTeam merely discloses that approving users may or may not through a workflow process electronically sign records.

Moreover, the Office Action points to section 2.3 of SmartTeam in support of a prima facie case of anticipation. However, section 2.3 of SmartTeam merely indicates that two users cannot have the same user login, and that the SmartTeam software implementation team will comply with the certification requirement of rule 11.100. The Office Action fails to provide any discussion of how section 2.3 that compliance with the FDA rule that no two users have the same login and the fact that the software team anticipates compliance with the rule applies to the above-recited claim limitations.

In light of the above, Applicants respectfully submit that SmartTeam fails to teach or suggest each and every claim limitation as recited in claim 1. Thus, Applicants respectfully submit that claim 1 is allowable over the cited references.

**Claim 2**

Claim 2 recites that an application program interface comprises an event name and an event id. The Office Action points to sections 2.2-2.3 of SmartTeam for allegedly disclosing the above recited feature. Applicants respectfully disagree.

37 C.F.R. § 1.104(c)(2) states that "when a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable." Applicants respectfully submit that merely pointing to sections 2.2-2.3 of SmartTeam fails to designate as nearly as practicable the alleged teachings in SmartTeam. However, Applicants respectfully submit that SmartTeam fails to teach or suggest an application program interface that comprises an event name and an event id as recited in claim 1.

For example, section 2.2 discloses that the software tracks the user performing the operation, the timestamp of the new record, and the type of operation. None of these, individually or in combination, teach or suggest that an application program interface comprises an event name and an event id as recited in claim 2.

Furthermore, the Approval function in section 2.2 discloses that the full name of the signing user, the timestamp of the signature, and a meaning are kept on the record. None of these, either individually or in combination, teach or suggest an application program interface that comprises an event name and an event id as recited in claim 2.

Moreover, the server side mechanism in section 2.2 merely integrates the signature into managed files.

Additionally, the audit trail in section 2.2 includes the full name of the signer, the date and time, and the meaning of the operation. However, none of these, either individually or in combination, teach or suggest an application program interface that comprises an event name and an event id as recited in claim 2.

The bottom box of section 2.2 indicates that the SmartTeam software saves the user information on the records. Merely saving information to provide an audit trail as in section 2.2 of SmartTeam fails to teach or suggest an application program interface that comprises an event name and an event id as recited in claim 2.

In light of the above, Applicants respectfully submit that claim 2 is allowable over the cited references.

**Claim 2-24**

Applicants respectfully submit that independent claims 11 and 20 are allowable for at least a similar rationale as discussed above for the allowability of claim 1, and others. Applicants respectfully submit that dependent claims 2-10, 12-19, and 21-24 that depend directly and/or indirectly from the independent claims 1, 11, and 20 respectively, are also allowable for at least a similar rationale as discussed above for the allowability of the independent claims. Applicants further respectfully submit that the dependent claims recite additional features that make the dependent claims allowable for additional reasons.

## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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